



(19) Europäisches Patentamt
European Patent Office
Office européen des brevets



(11) Publication number:

0 448 204 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication of patent specification: **26.04.95** (51) Int. Cl.⁶: **A61M 15/00**

(21) Application number: **91300895.9**

(22) Date of filing: **04.02.91**

(54) **Inhaler device with counter and timer means.**

(30) Priority: **20.02.90 US 482155**

(43) Date of publication of application:
25.09.91 Bulletin 91/39

(45) Publication of the grant of the patent:
26.04.95 Bulletin 95/17

(64) Designated Contracting States:
BE CH DE FR GB LI NL

(56) References cited:
WO-A-86/05991
WO-A-87/05813
US-A- 4 817 822

(73) Proprietor: **Dessertine, Pauline L.**
53 Park Avenue
Flemington,
New Jersey 08822 (US)

(72) Inventor: **Dessertine, Pauline L.**
53 Park Avenue
Flemington,
New Jersey 08822 (US)

(74) Representative: **Ablewhite, Alan James et al**
MARKS & CLERK,
57/60 Lincoln's Inn Fields
London WC2A 3LS (GB)

EP 0 448 204 B1

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid (Art. 99(1) European patent convention).

Description

The present invention is directed to inhalers for the controlled inhalation of medication by a patient by self-activation. More particularly, it is directed to an inhaler which receives inhalation canisters for manual release of pressurized medication in spray form into the mouth and the inhaler is adapted to include counting and timing capabilities to enhance proper self-administration of doses by patient.

The use of inhalers is well known and the art has developed over the past twenty years to cover many versions of the basic concept of a "pumping" type medication applicator. The device is not truly pumped although a pumping like cycle is utilized. The medication is repeatedly released from a disposable canister, e.g. by depressions by the patient to create repeated sprays or inhalations as needed.

U.S. Patent No. 3,361,306 to W.M. Grim illustrates a typical inhaler where a canister of medication is inserted into the back end of a device and the spray nozzle of the canister sits in a spray-directing member to shoot spray out of the front (mouth) end of the device when the canister is pressed down by a user.

US Patent No. 3,183,907 describes an inhaler in which a button on its underside is pushed by the user to release a controlled or metered amount of spray from a medication canister held in the top or back end of the inhaler.

US Patent No. 4,817,822 to Paul Rand et al describes an inhaler device which includes counting means for indicating the relative emptiness of a container or the number of doses dispensed. However, this inhaler counting mechanism is attached to the medicine container as well as the inhaler, such as by a retaining ring or retaining cap and is preferably not removed from the container.

A further example of the prior art devices is given in WO-A-87/05813.7

Notwithstanding the prior art, the use of counters for an exact count of sprays per application, e.g. five sprays or six sprays each time the device is used, is not taught nor rendered obvious by the prior art, nor is the use of a timer to enable the user to control the elapsed time, e.g. 60 seconds, between each spray of a multispray application, as in the present invention.

The present invention is as defined in the claims and is directed to a device for inhaling medicine from an inhalation canister with a spray stem. It includes a hollow-bodied tubular main body having a back end adapted to receive an inhalation canister and a front end adapted for placement to or in a mouth, as well as a spray-directing element fixedly located within the main body, a counter and a timer. The spray-directing

5 element has a continuous opening with an insert end for receiving a spray stem of an inhalation canister and a spray end for directing sprays of medicine through and out of the front end of the main body when an inhalation canister is activated by a user. The counter is connected to the main body for displaying a count of total activations of an inhalation canister and is advanced by each activation of an inhalation canister. The timer keeps track of time between inhalations for the user. Both the counter and the timer are resettable and are preferably electronic and may be contained in a single unit.

10 The present invention is more fully understood when this specification is taken in conjunction with the drawings which are appended hereto, and wherein:

15 Figure 1 shows a side cut view of a present invention inhaler with a medication canister inserted therein;

Figure 2 illustrates a full front view of the device shown in Figure 1;

Figure 3 shows an alternative embodiment present invention inhaler in actual use; and

20 Figure 4 shows a front oblique view of the counter/timer unit shown on the Figure 3 inhaler device.

25 The sufferer of asthma or other respiratory ailments has frequent need for relief from breathing and other difficulties and the use of hand-held inhalers brings frequent relief. These devices sometimes have moving parts, but all are based on three principles. First, the device receives loaded, disposable canisters of medication which today are pressurized but may alternatively be true pump type dispensers. Second, the inhaler holds the canister while the canister outlet is seated in, directed to or connected to a spray directing element. Third, the user presses something, either the canister, a button on the inhaler or a combination, to effectuate a required discharge.

30 While the inhaler has brought relief to many patients, some must take repeated dosages at a given application for a specific number of sprays at specified time intervals. Thus, a patient may need, e.g., seven sprays taken at sixty second intervals. However, when an asthma attack occurs, and inhaler relief is needed or even when periodic medication is taken, it is difficult for the patient to keep track of the number of sprays and/or the elapsed time between each spray.

35 40 45 50 55 The present invention is directed to aiding the patient by providing counting means and timing means built into the inhaler itself. It is the use of these additions to the inhaler that enables the patient to effectively and efficiently use the inhaler in many situations, e.g. at home, on the job in a manual labor environment, while driving or holding

a baby, etc.

The particular internal mechanism is now within the purview of the artisan and not discussed in detail. In other words, electronic stop watches, timers and counting mechanisms are known and available. It is the particular application to the inhaler that constitutes the critical features herein.

Referring now to Figure 1, there is shown a side cut view of inhaler 1, having a hollow main body 2, with back end 3 adapted to receive an inhalation canister, and a front end 5 adapted for placement to or in a mouth (although, without exceeding the scope of the invention, it could be for placement relative to the mouth and nostrils or nostrils). Spray-directing element 7 is fixedly located within main body 2, as shown, and includes a continuous opening 9. The opening 9 has an insert end 11 for receiving-a spray stem 17 of an inhalation canister 15, and has a spray end 13 for directing sprays or puffs of medicine through and out of the front end 5 of main body 2 when canister 15 is activated by a user.

Referring now to both Figures 1 and 2, like parts are like numbered as Figure 2 shows a full front view of the inhaler 1 of Figure 1. Unit 21 includes an automatic counter chip with a long-life miniature battery (not shown) and a timer (not shown) which is activated by downward movement of canister 15 against lever 23, which is connected to unit 21. Lever 23 is located so as to pass through orifice 25 and is movable therein. Each time the user depresses canister 15, lever 23 swings downward and ticks off one more count, which is displayed at LCD 27. Additionally, the timer is activated simultaneously therewith and signals a "beep" sixty seconds after lever 23 is depressed. When a user is finished with the correct number of sprays at, in this case, sixty second intervals, the unit 21 may be simultaneously stopped and reset by depressing reset button 29.

While the device of Figures 1 and 2 has an audible signal, it could alternatively be visual or combined audio-visual. Likewise, separate reset buttons and controls for the counter and the timer could be used without exceeding the scope of the present invention.

Also, the length of the elapsed time could be preset at an interval different from sixty seconds, and could be programmable, although it is preferred to be preset to simplify its use.

While Figures 1 and 2 show an inhaler having no moving parts other than the lever, the present invention could include a pump or a push button or have other features used in available inhalers without exceeding the present invention scope.

Figure 3 shows an alternative embodiment of the present invention. User 35 has inhaler 39 in hand 37 in this inhaler 39, push button 47 is

5 depressed to activate canister 45, held firmly in place, and button 47 pushes in a spray stem (not shown) of canister 45 to effectuate a spray. Mouth-piece 43 is inserted as shown with back end 41 receiving canister 45. Combined unit 49 includes dual features and may be activated by lever, button, electrical contact being completed by a metal canister 45, or by any other known mechanism within the purview of the artisan.

10 Figure 4 shows the details of unit 49 of Figure 3. Unit 49 has a curved back 51 for attachment to inhaler 39 by known plastic-to-plastic means, although the inhaler and/or unit may be metal or metal-plastic and known assembly techniques may be used. Unit 49 includes counter with display 53 and timer with display 55. Reset buttons 57 and 59 are also included.

15 Since manufacturers today sell or provide inhalers with the medication which are disposable, the present invention inhaler may include a counter/timer unit which is detachable and is usable with many inhalers which are adapted to have the counter/timer unit removably attached thereto. Such embodiments would be included within the scope of the invention. For example the counter/timer unit shown in Figures 3 and 4 could be removable with a snap on feature (not shown) or any other known attachment means.

20 30 Claims

1. A device (1) in the form of a spray dispenser for medicine from an inhalation canister (15) with a spray stem (17) which comprises:
25 (a) a hollow-bodied tubular main body (2) having a back end (3) adapted to receive the inhalation canister (15) and a front end (5) adapted for placement to or in a mouth or nose;
30 (b) a spray-directing element (7) fixedly located within said main body (2), and having a continuous opening (9) with an insert end (11) for receiving the spray stem (17) of the inhalation canister (15) and a spray end (13) for directing sprays of medicine through and out of the front end (5) of said main body (2) when the inhalation canister (15) is activated by a user; and
35 (c) counting means connected to said main body (2) for displaying a count of total activations of the inhalation canister (15), said counting means being advanced by each activation of the inhalation canister (15) and being resettable to zero

40 45 50 55 characterised in that the device (1) further comprises electronic timer means connected to the main body (2) for signalling time periods between each activation of the inhalation can-

- ister (15), the timer means including audible, visual or audio-visual signal (55), a power source and a preprogrammed chip for signalling predetermined intervals of time, whereby the user is enabled to administer in one application a sequence of a chosen number of sprays at chosen intervals.
- 5
2. The device of claim 1 wherein said counting means is electronic and includes a display (53), a power source and a preprogrammed chip for counting and resetting.
- 10
3. The device of claim 2 wherein said counting means is advanceable by contact of the activated inhalation canister (15) with an advancing lever (23) which is connected to said counting means.
- 15
4. The device of claim 2 wherein said counting means is advanceable by closing or opening an electric circuit by contact of the activated inhalation canister (15).
- 20
5. The device of any of claims 1 to 4 wherein said counting means is removably connected to said main body (2).
- 25
6. The device of claim 1 wherein said counting means is a mechanical counter and is advanceable by contact of the activated inhalation canister (15) with an advancing ratchet or lever connected to said counting means.
- 30
7. The device of claim 6 wherein said mechanical counter has a reset button and is spring loaded such that it is resettable to zero by spring activation initiated by depression of said reset button.
- 35
8. The device of any of claims 1-7 wherein said counting means is manually advanceable by a user.
- 40
9. The device of claim 1 wherein said counting means and said timing means are contained in a single electronic unit (21, 49) which includes a display, a power source and a preprogrammed chip for counting, for signaling predetermined amounts of time and for resetting.
- 45
10. The device of claim 9 wherein said single electronic unit is removably connected to said main body.
- 50
- 55
- Patentansprüche**
- Vorrichtung (1) in Form eines Sprühspenders für Medizin aus einem Inhalationsbehälter (15) mit einem Sprühstab (17), welche folgende Komponenten aufweist:
 - einen rohrförmigen hohlen Hauptkörper (2) mit einem hinteren Ende (3), das den Inhalationsbehälter (15) aufnehmen kann, und mit einem vorderen Ende (5), das für die Plazierung an oder in einem Mund oder einer Nase geeignet ist;
 - ein Spray-Richtelement (7), das feststehend innerhalb des Hauptkörpers (2) angeordnet ist und eine durchgängige Öffnung (9) hat mit einem Einsatzende (11) zur Aufnahme des Sprühstabes (17) des Inhalationsbehälters (15) und einem Sprühende (13) zur Lenkung von Medizin-Sprays durch das und aus dem vorderen Ende (5) des Hauptkörpers (2), wenn der Inhalationsbehälter (15) durch einen Benutzer betätigt wird; und
 - ein Zählmittel, das mit dem Hauptkörper (2) verbunden ist, um eine Zählung der Gesamtzahl der Betätigungen des Inhalationsbehälters (15) anzuzeigen, wobei dieses Zählmittel bei jeder Betätigung des Inhalationsbehälters (15) vorgerückt wird und auf Null zurückgestellt werden kann, dadurch gekennzeichnet, daß die Vorrichtung (1) außerdem ein elektronisches Zeitmeßmittel aufweist, das mit dem Hauptkörper (2) verbunden ist, um die Zeitspannen zwischen den einzelnen Betätigungen des Inhalationsbehälters (15) zu signalisieren, wobei das Zeitmeßmittel ein akustisches, visuelles oder audio-visuelles Signal (55), eine Stromquelle und ein vorprogrammiertes Chip zur Signalisierung festgelegter Zeitintervalle einschließt, wodurch der Benutzer in die Lage versetzt wird, bei einer Anwendung eine Folge einer ausgewählten Zahl von Spraystoßen in ausgewählten Intervallen zu verabreichen.
 - Vorrichtung nach Anspruch 1, bei der das Zählmittel elektronisch ist und eine Anzeige (53), eine Stromquelle und ein vorprogrammiertes Chip zum Zählen und Rückstellen einschließt.
 - Vorrichtung nach Anspruch 2, bei der das Zählmittel durch Kontakt des betätigten Inhalationsbehälters (15) mit einem Vorrückhebel (23), der mit dem Zählmittel verbunden ist, vorgerückt werden kann.

4. Vorrichtung nach Anspruch 2, bei der das Zählmittel durch Schließen oder Öffnen eines Stromkreises durch Kontakt mit dem betätigten Inhalationsbehälter (15) vorgerückt werden kann. 5 pour diriger les pulvérisats de médicament à travers et en-dehors de l'extrémité avant (5) dudit corps principal (2) lors de l'actionnement du récipient pour inhalation (15) par un utilisateur; et
5. Vorrichtung nach einem der Ansprüche 1 bis 4, bei dem das Zählmittel abnehmbar mit dem Hauptkörper (2) verbunden ist. 10 (c) un moyen compteur connecté audit corps principal (2) pour afficher le nombre total d'actionnements du récipient pour inhalation (15), ledit moyen compteur étant avancé par chaque actionnement du récipient pour inhalation (15) et pouvant être remis à zéro,
6. Vorrichtung nach Anspruch 1, bei der das Zählmittel ein mechanisches Zählwerk ist und durch Kontakt des betätigten Inhalationsbehälters (15) mit einem Vorrück-Klinkenrad oder -hebel, die mit dem Zählmittel verbunden sind, vorgerückt werden kann. 15 caractérisé en ce que le dispositif (1) comprend en outre un moyen de minuterie électronique connecté au corps principal (2) pour signaler les périodes de temps écoulées entre chaque actionnement du récipient pour inhalation (15), le moyen de minuterie englobant un signal audible, visuel ou audio-visuel (55), une source d'énergie et une puce préprogrammée pour signaler les intervalles de temps prédéterminés, l'utilisateur pouvant ainsi administrer en une seule application une séquence d'un nombre voulu de pulvérisations à des intervalles voulus.
7. Vorrichtung nach Anspruch 6, bei der das mechanische Zählwerk einen Rückstellknopf hat und federbelastet ist, so daß es durch die Betätigung der Feder, die durch das Niederdrücken des Rückstellknopfes ausgelöst wird, auf Null zurückgestellt werden kann. 20
8. Vorrichtung nach einem der Ansprüche 1 bis 7, bei dem das Zählmittel durch einen Benutzer von Hand vorgerückt werden kann. 25
9. Vorrichtung nach Anspruch 1, bei der das Zählmittel und das Zeitmeßmittel in einer einzigen elektronischen Einheit (21, 49) enthalten sind, die eine Sichtanzeige, eine Stromquelle und ein vorprogrammiertes Chip zum Zählen, zum Signalisieren von festgelegten Zeitspannen und zum Rückstellen einschließt. 30
10. Vorrichtung nach Anspruch 9, bei der die einzige elektronische Einheit abnehmbar mit dem Hauptkörper verbunden ist. 35

Revendications

1. Dispositif (1) sous forme d'un distributeur pulvérisateur d'un médicament contenu dans un récipient pour inhalation (15), comportant une tige de pulvérisation (17), comprenant:
- (a) un corps principal tubulaire creux (2) avec une extrémité arrière (3) adaptée pour recevoir un récipient pour inhalation (15) et une extrémité avant (5), adaptée pour être placée sur ou dans la bouche ou le nez;
 - (b) un élément pour diriger le pulvérisat (7), agencé de manière fixe à l'intérieur dudit corps principal (2) et comportant une ouverture continue (9) avec une extrémité d'insertion (11) pour recevoir la tige de pulvérisation (17) du récipient pour inhalation (15), ainsi qu'une extrémité de pulvérisation (13) 40 pour diriger les pulvérisats de médicament à travers et en-dehors de l'extrémité avant (5) dudit corps principal (2) lors de l'actionnement du récipient pour inhalation (15) par un utilisateur; et
2. Dispositif selon la revendication 1, dans lequel ledit moyen compteur est électronique et englobe un affichage (53), une source d'énergie et une puce préprogrammée pour le comptage et la remise à zéro.
3. Dispositif selon la revendication 2, dans lequel le moyen compteur peut être avancé par suite du contact du récipient pour inhalation (15) actionné avec un levier d'avance (23), connecté audit moyen compteur. 45
4. Dispositif selon la revendication 2, dans lequel ledit moyen compteur peut être avancé par la fermeture ou l'ouverture d'un circuit électrique par suite d'un contact du récipient pour inhalation (15) actionné.
5. Dispositif selon l'une quelconque des revendications 1 à 4, dans lequel ledit moyen compteur est connecté de façon amovible audit corps principal (2). 50
6. Dispositif selon la revendication 1, dans lequel ledit moyen compteur est un compteur mécanique, pouvant être avancé par suite du contact du récipient pour inhalation (15) actionné avec un cliquet ou un levier d'avance connecté audit moyen compteur.
7. Dispositif selon la revendication 6, dans lequel ledit compteur mécanique comporte une tou-

che de remise à zéro et est chargé par ressort, de sorte qu'il peut être remis à zéro par l'intermédiaire de l'actionnement du ressort entraîné par un appui sur ladite touche de remise à zéro.

5

8. Dispositif selon l'une quelconque des revendications 1 à 7, dans lequel ledit moyen compteur peut être avancé manuellement par l'utilisateur.

10

9. Dispositif selon la revendication 1, dans lequel ledit moyen compteur et ledit moyen de minuterie sont contenus dans une seule unité électronique (21, 49), englobant un affichage, une source d'énergie et une puce préprogrammée pour le comptage et la signalisation des périodes de temps prédéterminées et pour la remise à zéro.

20

10. Dispositif selon la revendication 9, dans lequel ladite seule unité électronique est connectée de façon amovible audit corps principal.

25

30

35

40

45

50

55

6

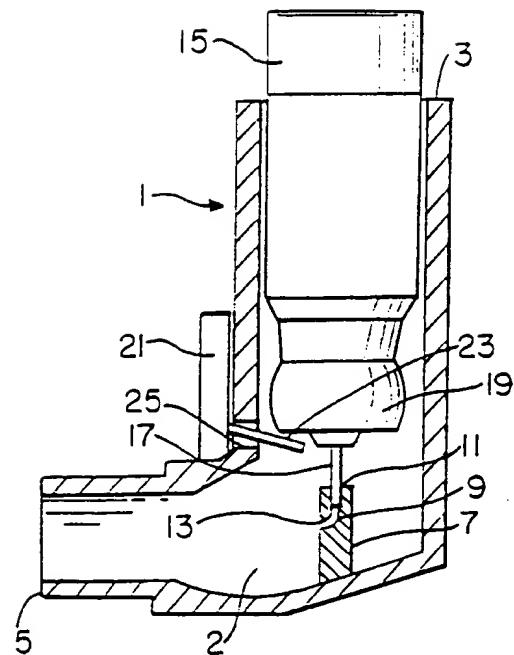


FIG. 1

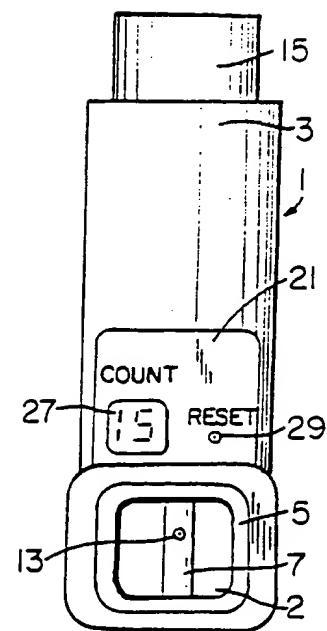


FIG. 2

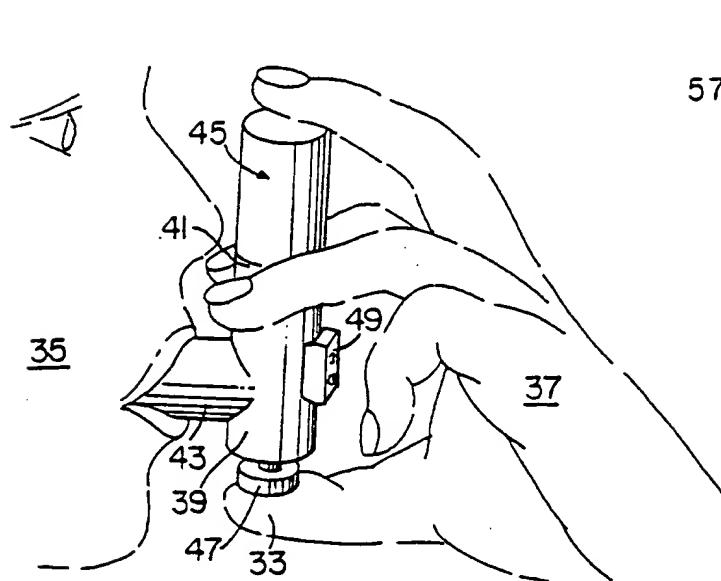


FIG. 3

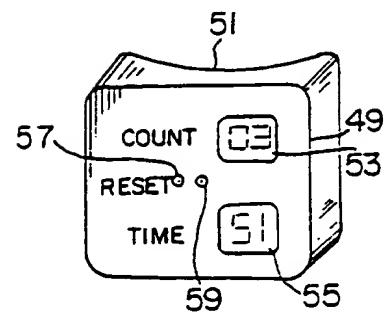


FIG. 4